UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Minnesota Pharmacists Association, *et al.*,

Plaintiffs,

v.

Timothy Pawlenty, not individually, but solely in his official capacity as Governor of the State of Minnesota; Cal Ludeman, not individually, but solely in his official capacity as Commissioner of the Minnesota Department of Human Services; Brian Osberg, not individually, but solely in his official capacity as Director of the Minnesota Medicaid Program; and the Minnesota Department of Human Services,

Defendants.

Civil No. 09-2723 (DWF/RLE)

MEMORANDUM OPINION AND ORDER

David M. Aafedt, Esq., and William A. McNab, Esq., Winthrop & Weinstine, PA; and Amy E. McCracken, Esq., Frederick R. Ball, Esq., Nichols J. Lynn, Esq., and Nina Russakoff, Esq., Duane Morris, LLP, counsel for Plaintiffs.

Patricia A. Sonnenberg, Assistant Attorney General, State of Minnesota, counsel for Defendants.

INTRODUCTION

This matter is before the Court on Plaintiffs' motion for a preliminary injunction (Doc. No. 13) and on Defendants' motion for judgment on the pleadings (Doc. No. 17).

For the reasons stated below, this Court grants in part and denies in part the motion for judgment on the pleadings and denies the preliminary injunction motion.

FACTUAL AND PROCEDURAL BACKGROUND

In this action against state officials for declaratory and injunctive relief, a variety of plaintiffs–chiefly pharmacies and associations representing pharmacies but also several Medicaid recipients–seek to reverse recent reductions in the reimbursement rates that the State of Minnesota pays pharmacies for brand-name ("single-source") pharmaceutical drugs covered by the State's Medicaid program.[1] The reductions result from two separate actions: (1) the State's amendment, effective July 1, 2009, of its Medicaid plan changing its reimbursement rate from Average Wholesale Price ("AWP") less 14 percent to AWP less 15 percent ("the one-percent cut" or "the July 1 cut"); and (2) the change, effective September 26, 2009, in the computation of AWP, a change which results not from any

[1] Plaintiffs include (1) several pharmacists' associations, (2) numerous pharmacies, and (3) three Medicaid beneficiaries. (Doc. No. 1, ¶¶ 6-21.) The pharmacies include: Astrup Drug, Inc; Coborn's Inc.; Falk's Pharmacies, Inc.; Genoa Health Minnesota, LLC; Goodrich Pharmacy, Inc.; JT Hoeschen Inc. (d/b/a St. Paul Corner Drug); Setzer Pharmacy, Inc.; Thrifty Drug Stores, Inc.; and Trumm, Drug, Inc. ("the Provider Plaintiffs"). (*Id.* ¶¶ 11-19.) The pharmacist associations include: National Association of Chain Drug Stores; National Community Pharmacists Association; Minnesota Retailers Association; and Minnesota Grocers Association ("the Association Plaintiffs"). (*Id.* ¶¶ 6-10.) The Medicaid recipients are Robert Diaz, and two minors, M.B. and A.H., represented by their legal guardian James Brech ("the Recipient Plaintiffs"). (*Id.* ¶¶ 20-21.) Defendants include three state officials solely in their official capacities (Governor Pawlenty, Cal Ludeman, the Commissioner of the Minnesota Department of Human Services, and Brian Osberg, the Director of the Minnesota Medicaid Program), and the Minnesota Department of Human Services ("the Department" or "DHS') (collectively, "the State").

overt legislative or executive decision of the State but rather from a settlement that the private publisher of AWPs entered into in other litigation in which it agreed to reduce its computation of AWP to Wholesale Acquisition Cost ("WAC") plus 20 percent (rather than 25 percent) ("the four-percent cut" or "the September 26 cut").

Congress created the Medicaid program in 1965 by amending the Social Security Act to add Title XIX. Pub. L. 89-97, Title I, § 121(a), 79 Stat. 244 (codified at 42 U.S.C. Chapter 7, Subchapter XIX); *see Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 650 (2003). Pursuant to its authority under the Spending Clause, Congress thus established a joint federal-state program to provide medical care to certain economically disadvantaged citizens. Although the States are not required to participate in the program, if they elect to do so, their plans must meet certain minimal federal requirements in order to get federal funding.

The federal statute at issue, governing "State plans for medical assistance," first imposes numerous requirements on any State plan. 42 U.S.C. § 1396a(a) (specifying detailed requirements in some 71 enumerated paragraphs). It then provides that the Secretary of Health and Human Services "shall approve any plan which fulfills the conditions specified in subsection (a) of this section, except that he shall not approve any plan which imposes, as a condition of eligibility for medical assistance under the plan[,]" any of three specified conditions not applicable here. *Id.* § 1396a(b). If the Secretary finds that a State plan fails "to comply substantially with any such provision" of Section 1396a, she shall terminate federal funds to the State. *Id.* § 1396c.

The particular provision at issue, Section 1396a(a)(30)(A), generally requires that payments under a State plan be "consistent with efficiency, economy, and quality of care" and also be "sufficient to enlist enough providers" so as to provide care and services at least equal to that "available to the general population in the geographic area." *Id.* § 1396a(a)(30)(A) ("Subsection (30)(A)").

The State of Minnesota participates in the program pursuant to its State plan as approved by the Secretary of Health and Human Services. Minnesota law provides that reimbursement of Medicaid providers of prescription drugs cannot exceed the lowest of three amounts: (1) the actual acquisition costs ("AAC") of the drugs plus a fixed dispensing fee; (2) the maximum allowable costs set by the federal government or by the Commissioner of the DHS plus a fixed dispensing fee; or (3) the usual and customary price charged to the public. Minn. Stat. § 256B.0625, subd. 13e(a). The State does not attempt to base reimbursement on the actual acquisition cost of each individual prescription filled for Medicaid recipients. Rather, it relies on estimates of such costs.

Until July 2009, the AAC was estimated as the AWP minus 14 percent. *Id.* To calculate the AAC, the State uses data from First DataBank, Inc., a private clearinghouse of pharmaceutical data, which publishes the AWP of numerous prescription drugs.

Recently, however, Minnesota, by statute duly enacted by the legislature and signed by Governor Pawlenty, changed its law governing the reimbursement rate it would pay Medicaid providers for prescription drugs and amended its State Medicaid plan accordingly. The State changed its reimbursement rate from AWP minus 14 percent to

AWP minus 15 percent, effective July 1, 2009. The Secretary of Health and Human Services approved Minnesota's plan amendment on November 18, 2009.[2]

Independent of this state legislative change in the reimbursement rate, Plaintiffs also challenge a separate reduction that stems from a change in a component of the formula that Minnesota, along with many other states, uses to calculate the applicable AAC of a particular prescription drug. That change results from a settlement that First DataBank entered in other litigation, by which, as relevant here, it agreed to reduce "its published AWP figures for all drug products . . . with a mark-up higher than 1.2 down to a 1.2 mark-up." *National Ass'n of Chain Drug Stores v. New England Carpenters Health Benefits Fund*, 582 F.3d 30, 37 (1st Cir. 2009). The First Circuit has summarized the drug pricing system as it operates generally, that is, not just in the Medicaid context:

> Drug manufacturers typically sell to drug wholesalers at a list price–called in the industry the "wholesale acquisition cost" ("WAC")–although discounts may be provided to the wholesaler . . . . Wholesalers add a mark-up in selling the drugs to retail pharmacies . . . . Pharmacies then add a mark-up of their own when they sell the drugs to consumers. . . . The insurer or its agent typically contracts with the pharmacy to reimburse the latter for the drugs it supplies to the beneficiary based on a discount (which will vary) from a notional benchmark price called the "average wholesale price" ("AWP"). The AWP figure is usually derived by applying a multiplier to the WAC for the drug, and publishers of AWP lists normally obtained their AWP figures from manufacturers or wholesalers. Historically, AWPs were derived by applying different mark-ups to

[2] Federal law permits a State to make changes to its Medicaid plan effective before obtaining federal approval. (Doc. No. 53, ¶ 10 (explaining that under 42 C.F.R. § 447.256(c) (2008), states may implement their proposed state plan amendments as early as the first day of the quarter in which an approvable amendment is submitted).)

> different drugs, the most common multiplier being 1.2 or 1.25–percentage mark-ups of 20 and 25 percent, respectively.
>
> Contracts between pharmacies and a [Third Party Payor or Pharmacy Benefit Manager] typically incorporate AWP prices by reference. Because the TPP or PBM normally contracts to reimburse pharmacies at a discount from AWP figures, the AWP supplied by a publisher for a drug is likely to be higher than the reimbursement paid by any TPP or PBM; but, given the pharmacy-TPP (or pharmacy-PBM) contract incorporating the AWP as the starting point, an increase in the published AWP means that the TPPs will pay more and the pharmacy will receive more.

Id. at 36. Following the First DataBank settlement, the State informed prescription drug providers participating in the Medicaid program that it would continue to reimburse them using the "revised AWP values." (Doc. No. 1, Ex. A.)

Plaintiffs' Complaint thus asserts the following claims: (1) a Section 1983 claim seeking declaratory relief for violation of their purported rights under Subsection (30)(A) (Count I); (2) a Supremacy Clause claim for injunctive relief regarding the July 1 cut (Count II); (3) a Supremacy Clause claim for injunctive relief regarding the September 26 cut (Count III); (4) a Supremacy Clause claim for declaratory relief regarding the July 1 cut (Count IV); (5) a Supremacy Clause claim for declaratory relief regarding the September 26 cut (Count V); (6) a state-law claim that Defendants breached the Provider Agreement via the September 26 cut (Count VI); (7) a state-law claim seeking a declaration that Defendants violated the Minnesota Constitution by breaching the Provider Agreement via the July 1 cut (Count VII); and (8) a state-law claim that Defendants' August 27, 2009 Provider Update violated the Minnesota Constitution's

Separation of Powers Clause by changing reimbursement rates without legislative approval (Count VIII). (Doc. No. 1, ¶¶ 61-109.)

Plaintiffs then promptly moved for a preliminary injunction. (Doc. No. 13.) After filing a joint Answer (Doc. No. 16), Defendants moved for judgment on the pleadings (Doc. No. 17). Finally, the United States of America has filed a Statement of Interest, contending that there is no requirement that the State submit a plan amendment to obtain approval of the four-percent cut resulting from the AWP settlement. (Doc. No. 66.)

DISCUSSION

In seeking a judgment on the pleadings, the State contends that (1) all claims against DHS are barred by the Eleventh Amendment; (2) the state-law claims (Counts VI, VII, & VIII) are also barred by the Eleventh Amendment; (3) Subsection (30)(A) does not confer any enforceable rights so as to support a Section 1983 claim; and (4) Plaintiffs cannot maintain an action based on the Supremacy Clause where the Secretary has approved the State plan. (Doc. Nos. 20, 61.) The State also argues that each category of Plaintiffs lack standing and that the Individual Provider and Individual Recipient Plaintiffs fail to allege sufficient facts to state a claim. (Doc. No. 20.)

I. Judgment On The Pleadings Standard

In resolving a motion for judgment on the pleadings under Rule 12(c), a court applies the same standard used to address a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009). In deciding a motion to dismiss pursuant to Rule 12(b)(6), a

court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged, *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id*. at 555. As the United States Supreme Court recently reiterated, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

But, of course, a motion under Rule 12(c) for judgment on the pleadings is addressed–as its name would suggest–to "the underlying substantive merits of the parties'

claims and defenses as they are revealed in the formal pleadings." 5C Wright and Miller, *Federal Practice and Procedure* § 1367, at 206 (3d ed. 2004). It thus differs from a motion to dismiss under Rule 12(b), which addresses either issues collateral to the merits, Rule 12(b)(1)-(5) (various jurisdictional defects), or issues of the formal sufficiency of the pleadings, Rule 12(b)(6) (failure to state a claim). *Id.* § 1369, at 258-59.

Moreover, because a motion for judgment on the pleadings is addressed to the merits, it is similar to a motion for summary judgment but is properly raised any time after the answer has been filed, while a summary judgment motion is frequently deferred until after the completion of discovery. *See id.* at 261. Thus, because a motion for judgment on the pleadings is properly sought before discovery, it thereby imposes the deferential factual standard of a motion to dismiss. *Id.* § 1368, at 238-48. In sum, where the defendant moves for judgment on the pleadings, the court must accept as true all factual allegations set out in the complaint and such a judgment "is appropriate only when there is no dispute as to any material facts and the moving party is entitled to judgment as a matter of law." *Wishnatsky v. Rovner*, 433 F.3d 608, 610 (8th Cir. 2006).

II. Defendants Are Largely Entitled To Judgment On The Pleadings

In light of the applicable standard, Plaintiffs' particular claims can be addressed as follows: (1) whether Plaintiffs may maintain a claim under Section 1983 for violation of Subsection (30)(A) (Count I); (2) whether Plaintiffs may maintain any of their claims under the Supremacy Clause based on an alleged conflict between the State plan and federal Medicaid law (Counts II, III, IV & V); and (3) whether Plaintiffs may maintain

any of their claims based on state law (Counts VI, VII & VIII) despite principles of state sovereign immunity.

Here, even accepting as true the factual allegations of Plaintiffs' Complaint, each of these issues may be resolved as a matter of law in Defendants' favor, with one exception. Because Plaintiffs have brought this action in federal court against State officials and against a State department–a fact which triggers issues of federalism, immunity from suit, and the Eleventh Amendment–the Court begins with this last group of claims, the three Counts premised on state law.

A. State Immunity From Suit In Federal Court And The Eleventh Amendment

Defendants first contend that all claims against the DHS are barred by the Eleventh Amendment.[3] The Supreme Court has construed the Eleventh Amendment, which by its express terms applies only to actions against states by citizens of other states, to nevertheless also bar suits in federal court against a state by its own citizens. *Edelman v. Jordan*, 415 U.S. 651, 662-63 (1974). Moreover, the immunity afforded a state in federal court extends to agencies of the state. *Florida Dept. of Health & Rehabilitative Servs. v. Florida Nursing Home Assn.*, 450 U.S. 147 (1981). Thus, all claims against the Department must be dismissed. *Pennhurst State School & Hosp. v. Halderman*, 465 U.S.

[3] The Court notes that Plaintiffs concede that the Eleventh Amendment bars their claims against the Department and that this concession is their entire opposition to Defendants' Eleventh Amendment argument, even though Defendants thereby also seek the dismissal of Plaintiffs' state-law claims regardless of whether such claims are directed at the Department or at the individual official Defendants.

89, 100-01 (1984) ("It is clear, of course, that in the absence of consent a suit in which the State or one of its agencies or departments is named as the defendant is proscribed by the Eleventh Amendment."). That Plaintiffs here seek only declaratory and injunctive relief does not evade this immunity. *Id.* ("This jurisdictional bar applies regardless of the nature of the relief sought.").

Finally, while the Supreme Court has long recognized an exception to Eleventh Amendment immunity permitting suits in federal court against state officials alleged to have violated federal law, at least where the relief sought is only injunctive, *Ex Parte Young*, 209 U.S. 123 (1908), that exception does not extend to allow such suits based on pendent state-law claims even if the relief sought is limited to prospective injunctive relief, *Pennhurst State School & Hosp.*, 465 U.S. at 105-06 ("We conclude that *Young* and *Edelman* are inapplicable in a suit against state officials on the basis of state law.").

Accordingly, the Court concludes (and the Plaintiffs concede) that the Eleventh Amendment bars their claims against the Department (based on any and all of the particular Counts of their Complaint). The Court further concludes that the same constitutional prohibition likewise precludes Plaintiffs' state-law claims (Counts VI, VII, and VIII). In sum, the Department is dismissed from this action, and Counts VI through VIII are similarly dismissed in their entirety against all Defendants. The Court thus turns

its attention to the claims in Counts I through V against the three state officials premised on federal law.[4]

B. Section 1983 And Enforceable Federal Rights

Count I, seeking declaratory relief, is a claim under Section 1983 alleging the violation of Plaintiffs' purported rights under Subsection (30)(A). Any citizen may bring an action against a person acting under color of state law for the "deprivation of any rights, privileges, or immunities secured by the Constitution and laws" of the United States. 42 U.S.C. § 1983. The Supreme Court has clarified, however, that to be entitled to the remedy provided by Section 1983–which "merely provides a mechanism for enforcing individual rights 'secured' elsewhere," because Section 1983 "'by itself does not protect anyone against anything'"–the underlying federal law that a plaintiff alleges was violated must have clearly conferred enforceable personal rights. *Gonzaga Univ. v. Doe*, 536 U.S. 273, 276 (2002). Specifically, only an "unambiguously conferred right" may support a Section 1983 action. *Id.*

The Eighth Circuit, however, has ruled–albeit in a pre-*Gonzaga* decision–that Subsection (30)(A) supported an action under Section 1983. *Arkansas Medical Society, Inc. v. Reynolds*, 6 F.3d 519 (1993). Plaintiffs contend that this Court is bound to adhere

---

[4] Under the doctrine of *Ex parte Young*, 209 U.S. 123 (1908), such actions–based on claims under federal law and seeking only prospective injunctive or declaratory relief against state officers in their official capacity–are not barred by the Eleventh Amendment. *Verizon Maryland Inc. v. Public Service Commission of Maryland*, 535 U.S. 635, 645-46 (2002).

to *Reynolds* as controlling Eighth Circuit authority. Defendants argue that *Gonzaga* no longer permits any such reliance. They further suggest that if there is any doubt as to the current validity of the decision in *Reynolds* after *Gonzaga*, this Court should certify the issue to the Eighth Circuit for resolution of whether *Reynolds* remains binding precedent.

But this Court sees no need to certify the question because *Gonzaga* is clearly an intervening decision that plainly negates the analytical basis on which *Reynolds* relied, particularly the "intended beneficiary" or "general zone of interest" analysis derived from earlier Supreme Court decisions that *Gonzaga* rejected in favor of the "unambiguously conferred rights" requirement.

1. The Supreme Court's "Enforceable Personal Rights" Framework

In *Gonzaga*, the Court granted certiorari "to resolve any ambiguity" in its prior opinions on the question of when a federal statute, enacted pursuant to Congress's authority under the Spending Clause, created individual rights enforceable under Section 1983. 536 U.S. at 278. Unlike, for example, constitutional provisions that plainly accord enforceable individual rights, federal statutes enacted under the Spending Clause "provide no basis for private enforcement" under Section 1983 "unless Congress 'speak[s] with a clear voice,' and manifests an 'unambiguous' intent to confer individual rights." *Id.* at 280.

For example, the *Gonzaga* Court explained that in *Wright v. Roanoke Redevelopment and Housing Authority*, 479 U.S. 418 (1987), it "allowed a § 1983 suit by

tenants to recover past overcharges under a rent-ceiling provision of the Public Housing Act, on the ground that the provision unambiguously conferred 'a mandatory [benefit] focusing on the individual family and its income.'" *Id.* Likewise, in *Wilder v. Virginia Hospital Association,* 496 U.S. 498 (1990), the Court allowed a Section 1983 action by "health care providers to enforce a reimbursement provision of the Medicaid Act, on the ground that the provision, much like the rent-ceiling provision in *Wright*, explicitly conferred specific monetary entitlements upon the plaintiffs." 536 U.S. at 280.

More recently, however, the Court has "rejected attempts to infer enforceable rights from Spending Clause statutes." *Gonzaga*, 536 U.S. at 281. The Court explained that it had rejected a Section 1983 action seeking to enforce the Adoption Assistance and Child Welfare Act of 1980 because it "conferred no specific, individually enforceable rights." *Id.* (citing *Suter v. Artist M*, 503 U.S. 347 (1992)). That federal statute–which "required States receiving funds for adoption assistance to have a 'plan' to make 'reasonable efforts' to keep children out of foster homes"–plausibly imposed "only a rather generalized duty on the State, to be enforced not by private individuals, but by the Secretary" by reducing payments. *Id.*

The *Gonzaga* Court further noted that in *Blessing v. Freestone*, 520 U.S. 329 (1997), it also had rejected a Section 1983 action seeking to enforce rights under Title IV-D of the Social Security Act because the federal statute–which "required States receiving federal child-welfare funds to 'substantially comply' with requirements designed to ensure timely payment of child support"–hardly created "an *individual*

entitlement to services" but rather provided a standard that "is simply a yardstick for the Secretary to measure the *systemwide* performance of a State's" program. *Gonzaga*, 536 U.S. at 281-82 (quoting *Blessing*, 520 U.S. at 340-43). "Because the provision focused on 'the aggregate services provided by the State,' rather than 'the needs of any particular person,' it conferred no individual rights." *Id.* at 282.

The *Gonzaga* Court thus concluded that such actions may proceed only where the right is "unambiguously conferred," because

> Section 1983 provides a remedy only for the deprivation of "rights, privileges, or immunities secured by the Constitution and laws" of the United States. Accordingly it is *rights*, not the broader or vaguer "benefits" or "interests," that may be enforced under the authority of that section.

536 U.S. at 283 (emphasis in original). The Court rejected any understanding of its decisions permitting "plaintiffs to enforce a statute under § 1983 so long as the plaintiff falls within the general zone of interest that the statute is intended to protect." *Id.*

Drawing an analogy to suits under an implied right of action, the Court clarified that both enforcing a statutory violation under Section 1983 and determining whether a private right of action can be implied from a particular federal statute first require a determination that "Congress *intended to create a federal right*," which requires that the statutory text "be 'phrased in terms of the persons benefitted.'" *Id.* "Accordingly, where the text and structure of a statute provide no indication that Congress intends to create

new individual rights, there is no basis for a private suit, whether under § 1983 or under an implied right of action." *Id.* at 286.[5]

2. Subsection (30)(A)–the Equal Access Provision

Here, Plaintiffs attempt to premise their Section 1983 claim on the alleged violation of the provision of the Medicaid Act that dictates a particular requirement for any State medical assistance plan. Such a plan must meet many requirements, including that it

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in Section 1986b(i)(4) of this title) *as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to*

---

[5] Some courts, and Plaintiffs here, contend that because the Supreme Court in *Gonzaga* did not expressly overrule *Wilder*, which permitted a Section 1983 action based on an alleged violation of a different requirement under Section 1396a(a), that the reasoning of *Wilder*–and by extension that of the Eighth Circuit's decision in *Reynolds*, which relied substantially on *Wilder*, remain valid. But the Court need not have expressly overruled *Wilder* in order to clarify–and narrow–its doctrine of enforceable individual rights, which it clearly did. The Court retained the *judgment* of *Wilder*, but on the grounds that the particular provision at issue "explicitly conferred specific monetary entitlements upon the plaintiffs." 536 U.S. at 280. While one court has suggested that the *Gonzaga* Court did not direct any "criticisms or clarification" at *Wilder*, *Missouri Child Care Ass'n v. Martin*, 241 F. Supp. 2d 1032, 1041 (W.D. Mo. 2003), it is clear that the Court rejected some implications of *Wilder* in that it clarified that, contrary to what *Wilder* might suggest, the Court's implied right of action cases are in fact relevant to the Section 1983 enforceable rights analysis. *Gonzaga*, 536 U.S. at 283. Perhaps more importantly, the *Gonzaga* Court plainly rejected the broader "benefit" test–which the Court expressly identified as having been employed in *Wilder* (and *Blessing*)–in favor of the narrower "unambiguously conferred right" analysis that now governs. *Id.* at 282.

> *the extent that such care and services are available to the general population in the geographic area.*

42 U.S.C. § 1396a(a)(30) (emphasis added) ("the Equal Access provision"). In essence, a state plan must employ methods and procedures regarding the use of and payment for medical care to ensure that reimbursements are sufficient to attract provider participation comparable to that outside of the program, but without compromising efficiency and economy of care.

In support of their argument that they can pursue a remedy under Section 1983, Plaintiffs rely on the Eighth Circuit's 1993 decision in *Arkansas Medical Society, Inc. v. Reynolds*, 6 F.3d 519 (8th Cir. 1993). In *Reynolds*, the court held that Medicaid providers, recipients, and related associations had sufficiently specific rights under the Equal Access provision to be able to pursue federal remedies under Section 1983. *Id.*

In *Reynolds*, however, the Eighth Circuit was guided (and bound) by the Supreme Court's extant decisions at that time–that is, 1993. The Eighth Circuit relied extensively on the Court's 1990 decision in *Wilder v. Virginia Hospital Association*, 496 U.S. 498 (1990), as supplemented–or perhaps slightly modified–by the 1992 decision in *Suter v. Artist M.*, 503 U.S. 347 (1992). Under what it discerned as the then-existing framework delineated by the Court's decision in *Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103 (1989), the Eighth Circuit "synthesize[d]" *Wilder* and *Suter* "by proceeding with the two-step *Golden State* analysis used in *Wilder*, bearing in mind the additional

considerations mandated by *Suter*." 6 F.3d at 525.[6] The Eighth Circuit noted that the Supreme Court's decision in *Wilder* "greatly simplified" resolution of the particular issue because *Wilder* also addressed Section 1396a (although not the Equal Access provision but rather a different requirement for state plans under that section, the Boren Amendment of Subsection (13)(A), a provision later repealed). *Id.* at 525.[7]

The Eighth Circuit first ruled that both Medicaid recipients and providers were "the *intended beneficiaries* of the equal access provision" because that provision was "indisputably intended to benefit" recipients by "allowing them equivalent access to health care services" and also was intended to benefit providers because it, like the Boren

---

[6] The Eighth Circuit relied on four observations: "First, *Suter* did not create an analytical framework to replace *Golden State*. Second, *Suter* did not overrule *Wilder*. Third, *Suter* placed great emphasis on the fact that rights must be 'unambiguously' conferred to be enforceable. And fourth, *Suter* emphasized that each statute must be examined on its own basis." *Id.* The court thus disagreed with those commentators that "have found *Suter* and *Wilder* difficult to reconcile." *Id.* In *Gonzaga*, however, the Supreme Court recognized that part of the confusion regarding its Section 1983 Spending Clause decisions was due to the fact that "*Wilder* appears to support" the notion that its implied private right of action cases have no bearing" on the Section 1983 issue, "while *Suter* . . . appear[s] to disavow it." 536 U.S. at 283. The Court granted certiorari precisely to resolve such ambiguities in its prior decisions. *Id.* at 278.

[7] Other courts have since concluded that there are substantial differences–indeed decisive differences for purposes of the Section 1983 question–between the numerous requirements under Section 1396a(a). *E.g., Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50, 56-57 (1st Cir. 2004) ("Subsection (30)(A), unlike subsection (13)(A), has no 'rights creating language' and identifies no discrete class of beneficiaries."). Thus, "[a]lthough *Gonzaga* did not overrule *Wilder*'s construction of the now repealed Boren amendment, *Gonzaga* requires clear statutory language for the creation of private rights enforceable under section 1983 at least where based upon federal funding statutes. . . . Subsection (30)(A) does not provide explicit rights for providers." *Id.* at 58.

Amended at issue in *Wilder*, "concerned their reimbursement." *Id.* at 525-26 (emphasis added). The court also found "sufficient mandatory language in the statute to create a binding obligation on the state" because the provision, like the Boren Amendment, was "introduced by the compulsory language '[a] State plan for medical assistance must . . .'" and, furthermore, was enforced by the Secretary's obligation to not approve funds under state plans "that do not conform to federal law." *Id.* at 526 & n.5.

The *Reynolds* court stated that it "must initially decide whether the plaintiffs are the intended beneficiaries of the equal access provision." 6 F.3d at 525. But the *Gonzaga* Court identified the confusion created in part by its focus in its earlier decision in *Blessing* on whether Congress had "'intended that the provision in question benefit the plaintiff.'" *Gonzaga*, 536 U.S. at 282. It then clarified that the issue was not whether "the plaintiff falls within the general zone of interest that the statute is intended to protect," but rather whether the federal statute "unambiguously conferred" *rights*, "not the broader or vaguer 'benefits' or 'interests." *Id.* at 283.

As the Ninth Circuit has concluded, "*Gonzaga* made it clear that simply being the intended beneficiary of a statute is not enough to demonstrate the intentional creation of an enforceable right." *Sanchez v. Johnson*, 416 F.3d 1051, 1062 (9th Cir. 2005). *Gonzaga*'s focus is thus plainly contrary to the Eighth Circuit's focus on Medicaid recipients and providers as the "intended beneficiaries" under the statute.

Moreover, Subsection(30)(A), like the particular statute at issue in *Gonzaga* and unlike the provisions identified by the *Gonzaga* Court as including "the sort of

'rights-creating' language critical to showing the requisite congressional intent to create new rights," directly addresses only the plan submitted by a particular State, not those persons that might derive some benefit from the plan. 42 U.S.C. § 1396a(a)(30)(A). In addition, Section 1396a(b) directs the Secretary of Health and Human Services to approve only State plans that fulfill the conditions of Section 1396a(a). As the *Gonzaga* Court explained, the focus of such a provision "is two steps removed from the interests of individual" Medicaid recipients and providers "and clearly does not confer the sort of '*individual* entitlement' that is enforceable under § 1983." 536 U.S. at 287 (emphasis in original).

3. Post-*Gonzaga* Decisions Regarding the Equal Access Provision

(A) The Eighth Circuit

After the 2002 decision in *Gonzaga*, the Eighth Circuit stated that its earlier decision in *Reynolds* was still valid. *Pediatric Specialty Care, Inc. v. Arkansas Dept. Of Human Services*, 443 F.3d 1005, 1014 (8th Cir. 2006) ("*Pediatric III*") ("[W]e do not read *Gonzaga* to require a different result than we reached in our earlier decisions [in *Pediatric Care*].").[8] But the Supreme Court vacated the relevant portion of that decision.

[8] In its 2006 decision in *Pediatric Specialty Care*, the third appeal in that action, the Eighth Circuit faced a law-of-the-case issue because it had earlier ruled in *Pediatric Specialty Care, Inc. v. Arkansas Dept. of Human Services*, 293 F.3d 472 (8th Cir. 2002) ("*Pediatrics I*"), that Subsection (13) created enforceable rights, and the court had ruled in *Pediatric Specialty Care, Inc. v. Arkansas Dept. of Human Services*, 364 F.3d 925 (8th Cir. 2004) ("*Pediatrics II*"), that Subsection (30)(A) had created enforceable rights. In *Pediatrics III*, the court concluded that *Gonzaga* did not dictate any (continued...)

Selig v. Pediatric Specialty Care, Inc., 551 U.S. 1142 (2007).[9]

Thus, insofar as whether *Reynolds* remains controlling authority, the issue appears to become whether *Gonzaga* is an intervening decision to the contrary. Granted, such an issue is best decided by the Eighth Circuit itself, but the doctrine of intervening controlling authority governs this Court too. *E.g., Phelps v. Alameida*, 569 F.3d 1120, 1133 (9th Cir. 2009) (noting that district court as well as three-judge appellate panel is bound by an intervening Supreme Court decision). This Court respectfully concludes that

---

[8](...continued)
deviation in the law of the case because that 2002 decision of the Supreme Court was "not an intervening decision," that is, it did not issue after *Pediatrics I* or *Pediatrics II*. 443 F.3d at 1014. The Eighth Circuit explained that the mandate in *Pediatric I* did not issue until eleven days *after Gonzaga* (even though the "decision in *Pediatrics I* was filed ten days" before *Gonzaga*) and the defendant had not filed any petition for rehearing. *Id.* Similarly, the "decision in *Pediatrics II* was not issued until April 16, 2004," such that the earlier *Gonzaga* decision could not be intervening. Here, however, the law-of-the-case doctrine is not at issue because the present action is obviously separate from the action that led to the three appeals in *Pediatric Specialty Care* and in this action there have been no prior decisions from this Court or the Eighth Circuit. And for purposes of this separate action, *Gonzaga*, decided in 2002, is clearly an intervening decision since the 1993 decision in *Reynolds*.

[9] Plaintiffs suggest that this has no relevant impact here because the Supreme Court vacated the judgment "with respect to the ***individual capacity claims*** against" two state officials. (Doc. No. 48 at 15 n.3 (emphasis in original).) But that portion of the decision–denominated as section "I" and regarding the qualified immunity of two state officials–was precisely the part of the decision addressing *Reynolds* and *Gonzaga*. 443 F.3d at 1012-16. The Supreme Court was simply clarifying that the portion of the judgment regarding state immunity from suit, the only other aspect of the Eighth Circuit's decision, was not vacated. In that portion, the Eighth Circuit had held that "[t]o the extent the plaintiffs' claims are against [the Arkansas Department of Human Services] they must be dismissed, but claims against the directors in their official capacity are not barred by the Eleventh Amendment." 443 F.3d at 1017.

the reasoning supporting the decision in *Reynolds* simply can no longer stand in the wake of the Supreme Court's clarification in *Gonzaga* of the narrowed scope of rights enforceable under Section 1983.

The Eighth Circuit appears to have confirmed as much in a decision that was issued shortly after *Pediatrics III*. In construing a different requirement for state plans under the Medicaid Act, specifically Section 1396a(a)(17), the Eighth Circuit ruled that the "reasonable-standards requirement" does not satisfy the requirements of *Gonzaga*. *Lankford v. Sherman*, 451 F.3d 496, 507-09 (8th Cir. 2006). The Eighth Circuit first noted that "[f]or legislation enacted pursuant to Congress's spending power, like the Medicaid Act, a state's non-compliance typically does not create a private right of action for individual plaintiffs, but rather an action by the federal government to terminate federal matching funds." *Id.* at 508 (noting that Supreme Court has only "rarely found enforceable rights in spending clause legislation").[10]

The *Lankford* court recognized that under *Gonzaga* "the statute must focus on an individual entitlement to the asserted federal right, rather than on the aggregate practices or policies of a regulated entity, like the state." *Id.* at 508-09. Agreeing with the Ninth

---

[10] Plaintiffs object to this "remedy" as "no remedy at all" for the Medicaid providers and recipients. (Doc. No. 48.) True enough, as a normative sentiment, but Plaintiffs' argument that the State's plan violates federal law is hardly supported by the reality–harsh though it may be for certain Plaintiffs–that Congress chose this mechanism to police state plans into compliance with federal law. *See* 42 U.S.C. §§ 1396 (noting that Medicaid funds shall be available "to States which have submitted, and had approved by the Secretary, State plans for medical assistance"), 1396a(b) (stating that Secretary shall approve State plans that satisfy "the conditions specified in subsection [1396a(a)]").

Circuit's decision in *Watson v. Weeks*, 436 F.3d 1152 (9th Cir. 2006), the Eighth Circuit held that the statutory language at issue failed that test because "the statute is not phrased in terms of the individuals it intends to benefit, as it lacks any reference to 'individuals' or 'persons,'" focusing instead "on the aggregate practices of the states in establishing reasonable Medicaid services." *Id.* at 509. And even if the statute would have focused on individual rights, "'the right it would create is too vague and amorphous for judicial enforcement.'" *Id.*

Here, too, Subsection (30)(A) focuses not on individual rights but rather on the "methods and procedures" a state must employ to ensure that "payments are consistent with the efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A). That provision "'requires each state to produce a *result*, not to employ any particular methodology for getting there.'" *Minnesota HomeCare Ass'n v. Gomez*, 108 F.3d 917, 919 (8th Cir. 1997) (Loken, J., concurring) (emphasis in original) (stating that plaintiffs had not stated a claim under § 1983 and questioning the result in *Reynolds*).

And the result that Subsection (30)(A) mandates does not reflect any individual right unambiguously conferred on Medicaid providers or recipients. Rather, by directing that state plans balance competing interests–"efficiency" and "economy" on one hand, against a reimbursement rate sufficient to attract provider participation on the

other–Section (30)(A) reflects a policy judgment regarding the States' administration of a program with multiple disparate goals more than it delineates concrete individual rights. *See Westside Mothers v. Olszewski*, 454 F.3d 532, 542-43 (6th Cir. 2006); *Sanchez v. Johnson*, 416 F.3d 1051, 1059-60 (9th Cir. 2005). As the Eighth Circuit has recognized, Subsection (30)(A) imposes a statutory duty on the Secretary of Health and Human Services to ensure that State Medicaid plans, while providing quality of care, also are efficient and economical. *Minnesota v. Centers for Medicare and Medicaid Servs.*, 495 F.3d 991, 996, 998 (8th Cir. 2007) (addressing efforts by Secretary to ensure that Minnesota's "plan amendment would be economical and efficient"). The factors of efficiency and economy–terms which, as undefined in the statutory framework, remain for the Secretary to interpret and apply in administering the system–hardly reflect any intent to simply accord enforceable rights in favor of either providers or recipients independent of countervailing interests. *Sanchez*, 416 F.3d at 1059-60 (explaining how "tension between" the "competing interests" supports "the conclusion that § 30(A) is concerned with overall methodology rather than conferring individual enforceable rights on individual Medicaid recipients"); *see Alaska Dept. Of Health and Social Servs. v. Centers for Medicare and Medicaid Services*, 424 F.3d 931, 940 (9th Cir. 2005) (affirming Secretary's rejection, based on statutory factors of efficiency and economy, of state plan that sought to increase payments to providers).

In any event, by dictating that State agencies develop plans that balance such competing interests, Subsection (30)(A) creates at most rights too vague and amorphous

for judicial enforcement. *Sanchez*, 416 F.3d at 1060. A provider's interest in reimbursement and a recipient's interest in medical care are only two of the several interests that a State is statutorily obligated to balance in developing a plan that complies with federal law. A court may review only the question of whether the overall plan satisfies Subsection (30)(A), not whether any discrete factor satisfies a particular litigant's independent self-interest.

(B) Other Federal Circuits

Moreover, since the Supreme Court in *Gonzaga* clarified the applicable analysis of whether a particular federal statute created rights that are enforceable in a Section 1983 action, all five of the federal circuits that have addressed the precise question here–whether the Equal Access provision of Subsection (30)(A) creates such enforceable rights–have ruled that no Section 1983 action was permissible. *Equal Access for El Paso, Inc. v. Hawkins*, 509 F.3d 697 (5th Cir. 2007); *Mandy R. v. Owens*, 464 F.3d 1139 (10th Cir. 2006); *Westside Mothers v. Olszewski*, 454 F.3d 532 (6th Cir. 2006); *Sanchez v. Johnson*, 416 F.3d 1051 (9th Cir. 2005); *Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50 (1st Cir. 2004). In fact, one of those circuits recognized that *Gonzaga*, whether "a tidal shift or merely a shift in emphasis," was a controlling intervening precedent that effectively negated that circuit's pre-*Gonzaga* decision to the contrary. *Long Term Care Pharmacy Alliance*, 362 F.3d at 58-59.[11]

[11] Although it is clear that the denial of certiorari is not precedential, the (continued...)

As the Fifth Circuit concluded, the "Equal Access provision does not create rights for individuals or an identifiable class. It speaks only to the State and the Secretary in their functions of proposing and approving a state plan" that complies with the provision's requirements. 509 F.3d at 703. "Thus, like the provisions at issue in *Gonzaga* and *Blessing*, the Equal Access provision speaks only in terms of institutional policy and practice, has an 'aggregate' rather than an individualized focus, and is not concerned with whether the needs of any particular person or class of individuals have been satisfied." *Id.* The Tenth Circuit came to the same conclusion, stating that "[r]ecipients and providers surely benefit from efficient Medicaid administration, . . . as do taxpayers generally, but subsection (30)(A) never establishes an 'identifiable class' of rights-holders." 464 F.3d at 1148 (expressly disagreeing with the Eighth Circuit's position in *Pediatrics III*).

Likewise, the Sixth Circuit ruled that in light of the fact that *Gonzaga* had clarified the first of the three requirements outlined in *Blessing*, Section 1396a(a)(30)(A) fails the first prong of that revised *Blessing* test because (1) it has "an aggregate focus rather than an individual focus" that "'is simply a yardstick for the Secretary to measure the *systemwide* performance of a State's [Medicaid] program'"; and (2) its "'broad and

---

[11](...continued)
Supreme Court has signalled no indication that the post-*Gonzaga* decisions from the various federal circuits regarding the Equal Access provision are wrong. *Equal Access For El Paso, Inc. v. Hawkins*, 129 S. Ct. 34 (2008) (denying certiorari petition without comment); *Mandy R. v. Ritter*, 549 U.S. 1305 (2007) (same).

nonspecific' . . . language" is "ill suited to judicial remedy" because it imposes "general objectives" that must be balanced against each other and because it addresses "'methods and procedures'" rather than "particular services." 454 F.3d at 542-43 (emphasis in original) (internal citations omitted).

Similarly, the Ninth Circuit has ruled that Subsection 1396a(a)(30)(A) "has an aggregate focus, rather than an individual focus" as it "speaks not of any individuals' right but of the State's obligation to develop 'methods and procedures' for providing services generally." 416 F.3d at 1059. While it refers to Medicaid providers, it does so "as a means to an administrative end rather than as individual beneficiaries of the statute." *Id.* Providers "may certainly benefit from their relationship with the State, but they are, at best, indirect beneficiaries and it would strain common sense to read [the provision] as creating a 'right' enforceable by them." *Id.* The court further observed that "[f]ar from focusing on the rights of a specific class of beneficiaries, § 30(A) is concerned with a number of competing interests" and that the "tension between these statutory objectives supports the conclusion that § 30(A) is concerned with over-all methodology rather than conferring individually enforceable rights on individual Medicaid recipients." *Id.* at 1059-60. In sum, "[t]he text and structure of § 30(A) simply do not focus on an individual recipient's or provider's right to benefits, nor is the 'broad and diffuse' language of the statue amendable to judicial remedy." *Id.* at 1060.

Finally, the First Circuit has ruled that whereas other requirements under Section 1396a(a) such as Subsection (13)(A) have "a narrow subject (rates for three

specified sets of services)" and confer "procedural rights on designated persons or entities (including 'providers'), subsection (30)(A) has much broader coverage, sets forth general objectives, and mentions no category of entity or person specially protected." 362 F.3d at 56. "Subsection (30)(A), unlike subsection (13)(A), has no 'rights creating language' and identifies no discrete class of beneficiaries." *Id.* at 57. The court concluded that the criteria of Subsection (30)(A) "are highly general and potentially in tension." *Id.* It further observed that "the generality of the goals and the structure for implementing them suggests that plan review by the Secretary is the central means of enforcement intended by Congress." *Id.* at 58.

Here, the Court concludes that under the analysis prescribed by the Supreme Court's 2002 decision in *Gonzaga*–which clearly rejects the "intended beneficiary" approach employed by the Eighth Circuit's 1993 decision in *Reynolds*–Subsection (30)(A) does not create any rights enforceable under Section 1983 by pharmacists, their associations, or Medicaid recipients. The State is thus entitled to judgment on Count I.

C. Supremacy Clause Claims

Counts II through V of Plaintiffs' Complaint are premised directly on the Supremacy Clause of the U.S. Constitution. The Supremacy Clause essentially provides that federal law preempts contrary state law. U.S. Const. art. VI, cl. 2. Plaintiffs claim that federal law–in particular the Equal Access provision of Subsection (30)(A)–preempts the State Plan as not meeting the requirements of that federal statutory provision.

The Supreme Court has ruled that an appropriate plaintiff has an implied cause of

action under the Supremacy Clause to challenge state law that is inconsistent with federal law. *E.g.*, *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n.4 (1983) ("It is beyond dispute that federal courts have jurisdiction over suits to enjoin state officials from interfering with federal rights."); *First Nat'l Bank of Eastern Ark. v. Taylor*, 907 F.2d 775, 776 n.3 (8th Cir. 1990) ("[T]he Supreme Court has since made clear that a party may apply directly to federal court for relief based on an affirmative claim of preemption.").

The preemption analysis is different, however, from that under Section 1983. *Lankford v. Sherman*, 451 F.3d 496, 509 (8th Cir. 2006) ("Preemption claims are analyzed under a different test than section 1983 claims, affording plaintiffs an alternative theory for relief when a state law conflicts with a federal statute or regulation."). Because the *Gonzaga* test for enforceable individual rights does not apply in the preemption context, an action under the Supremacy Clause alleging that a State Medicaid plan conflicts with federal law is not precluded by decisions holding that no enforceable individual rights exist under Subsection (30)(A). *E.g.*, *Independent Living Center of Southern Calif, Inc. v. Shewry,* 543 F.3d 1050, 1062 (9th Cir. 2008). Rather, the question is simply whether the State Plan is preempted because it conflicts with the requirements of Subsection (30)(A).

Plaintiffs contend that recent state and federal decisions "have explicitly held that state Medicaid reimbursement reductions that do not comply with Section 30(A)'s quality of care and access requirements are unlawful and preempted by the Supremacy Clause." (Doc. No. 48 at 18 (citing *Shewry*, 543 F.3d 1050; *Managed Pharmacy Care v.*

Maxwell-Jolly, 603 F. Supp. 2d 1230, 1235 (C.D. Cal. 2009); *Washington State Pharmacy Ass'n v. Gregoire*, 2009 WL 1259632 (W.D. Wash. Mar. 31, 2009).) But in *Shewry*, which Plaintiffs characterize as having "invalidated a Medicaid rate cut under the Supremacy Clause," *id.*, the Ninth Circuit simply reversed the district court's decision denying preliminary injunctive relief on the basis that the plaintiffs could not maintain any action under the Supremacy Clause because they had no enforceable individual rights under the Medicaid Act. 543 F.3d at 1052. The court confined its decision to addressing this "threshold reason" for the viability of a Supremacy Clause action, expressly taking no position "on the merits of [the plaintiff's] preemption claim." *Id.* at 1066.

Similarly, neither *Jolly* nor *Gregoire* ruled on the final merits of such claims but rather only granted preliminary injunctive relief. *Jolly*, 603 F. Supp. 2d at 1242 (granting preliminary injunction); *Gregoire*, 2009 WL 1259632 at *1 (granting temporary restraining order). A *preliminary* injunction based on a *likelihood* of success (much less a temporary restraining order) does not amount to a final and conclusive determination that Medicaid reimbursement rate reductions violate federal law. Moreover, none of those decisions disclose that the particular state reimbursement reductions had been approved by the federal Department of Health and Human Services.

Here, in contrast, Defendants contend that no such preemption challenge is possible because the federal government has approved the State Plan Amendment, as

required to obtain federal funds under the Medicaid Act.[12] Secretary Sebelius approved Minnesota's one-percent cut on November 18, 2009. (Doc. No. 53 (Aff. Of Ann Berg), Ex. 3.)

The Eighth Circuit has held that the disapproval of a State Medicaid plan by the federal Centers for Medicare and Medicaid Services' is set aside only if "it is arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law." *Iowa Dept. of Human Services v. Centers for Medicare and Medicaid Services*, 576 F.3d 885, 888 (8th Cir. 2009) (denying state's petition for review of Secretary's disapproval of state's plan proposing changes to Medicaid drug program). *Accord Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 661 (2003) (noting that if Secretary would reject State's amendment of its Medicaid plan, "the Secretary's ruling would be presumptively valid"). Likewise, the Secretary's approval in comparable circumstances would be entitled to deference under a similar standard. *State of New York v. Shalala*, 119 F.3d 175, 180 (2d Cir. 1997) ("Substantial deference is normally accorded to determinations made by the Secretary concerning the approval of [State Plan Amendments]".).

---

[12] Defendants have also disputed whether particular Plaintiffs here have standing to assert various claims. But the Court fails to see any defects in Plaintiffs' standing with respect to their Supremacy Clause claims because the reduction (or reductions) would constitute an injury-in-fact incurred by Plaintiffs and fairly traceable to the changes in the reimbursement rate. *Cf. Independent Living Center of Southern California, Inc. v. Shewry*, 543 F.3d 1050, 1064 (9th Cir. 2008) (finding that Medicaid providers and recipients had standing).

But in *Iowa Department of Human Services*, the Secretary's disapproval concerned whether the state's plan complied with *regulations* that the federal agency itself had promulgated. *Id.* (noting that it "must give substantial deference to an agency's interpretation of its own regulations"). Here, however, the question is whether Minnesota's plan complies with a federal *statute*, that is, Subsection (30)(A). But as the D.C. Circuit has ruled, the Secretary's interpretation of Section 1396a is reviewed "under the familiar and deferential two-part framework of *Chevron U.S.A., Inc. v. Natural Resources Defense Council*." *Pharmaceutical Research and Manufacturers of America v. Thompson*, 362 F.3d 817, 821 (D.C. Cir. 2004) (affirming summary judgment for Secretary of Health and Human Services on drug manufacturer organization's claims). The Secretary's decisions interpreting the Medicaid statute are entitled to *Chevron* deference because they "carry the force of law." *Id.* With respect to the Medicaid Act, the delegation of authority to the Secretary is not merely implicit "through the grant of general implementation authority." *Id.* at 821. Rather, Congress "expressly conferred on the Secretary authority to review and approve state Medicaid plans as a condition to disbursing federal Medicaid payments." *Id.* at 821-22.

There is no serious disagreement with the principle of law that an agency's interpretation of a statute it is charged with implementing is entitled to substantial deference. But this is not to say that agency decisions are insulated from any and all judicial review. Moreover, the present record does not afford this Court the factual basis to conclude at this early juncture of the proceedings, on a Rule 12(c) motion for judgment

on the pleadings, that the Secretary's approval is entitled to deference as a matter of law.

Granted, Defendants have submitted the Affidavit of Ann Berg, recounting the review process between the federal Center for Medicaid Services and the State's Department of Human Services concerning the State's amended plan. But that record does not reflect much, if any, explanation of the Secretary's position as to why the particular reimbursement reduction at issue here complies with Subsection (30)(A).

In contrast, Plaintiffs offer no substantive basis for questioning Secretary Sebelius' approval of the State Plan. Admittedly, the Secretary's approval did not occur until this action had been filed and the briefing on the two motions was underway. Nevertheless, Plaintiffs' Reply Memorandum filed on December 7, 2009, did not even mention, much less dispute the factual or legal basis for, the Secretary's November 18, 2009 approval as addressed in the State's November 30, 2009 response.

The resulting record thus appears somewhat one-sided at first, suggesting no basis for not deferring to the Secretary's approval. Lacking any showing as to errors in the agency decision-making process, the Court is aware of no persuasive, much less controlling, authority permitting it to substitute its assessment of whether the State Plan complies with Subsection (30)(A) for that of the federal agency that Congress expressly authorized to review and approve such plans. In fact, "the law grants significant weight to any legal conclusion by the Secretary as to whether a [State's] program . . . is consistent with Medicaid's objectives." *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 672-73 (2003) (Breyer, J., concurring in part and

concurring in judgment) (noting importance of courts in taking in views of federal agency that administers the Medicaid program as that agency "is better able than a court to assemble relevant facts . . . and to make relevant predictions").

But, as noted above, the State's showing evidences the fact of federal approval more than it discloses the analytic process of how the Secretary reached that result. While even the Secretary's conclusion alone should not be lightly disregarded, this Court's review of that decision–even under a deferential arbitrary and capricious standard–cannot proceed without a more substantial record of the Secretary's decision-making process. In light of the procedural posture of this action–a pre-discovery Rule 12(c) motion for judgment on the pleadings–and the significance of the dispute, the Court concludes that the better course is to defer a final decision on Plaintiffs' Supremacy Clause claims until the parties have an opportunity to develop a fuller record regarding the basis for the Secretary's approval of the State plan.

The Court also notes that the State Plan approved by Secretary Sebelius concerned only the one-percent cut. Plaintiffs also challenge the four-percent cut that results from the First DataBank settlement.[13] The State asserts that it "has never submitted a State

[13] Insofar as these two reductions differ in kind, it is not obvious that the two reductions should simply be lumped together so as to present a single integrated issue of whether the resulting "five-percent cut" satisfies the requirements of Subsection (30)(A). While the one-percent cut is a reduction from AWP, the four-percent cut reflects a modification in how AWP is calculated. This difference highlights the issue of whether the pre-modification computation of AWP accurately reflected the proper reference point for measuring pharmacies' actual acquisition costs, such that the deduction from that

(continued...)

Plan Amendment when AWPs change" and that CMS "has never required Minnesota to submit a State Plan Amendment in such situations." (Doc. No. 53, ¶ 8.)

The United States, which has filed a Statement of Interest pursuant to 28 U.S.C. § 517, contends that the reduction resulting from the settlement does not require the State to submit a plan amendment to CMS because a "change in the AWPs of particular products . . . does not constitute a change by Minnesota in its operation of its Medicaid program." (Doc. No. 66 at 6-7.) While Minnesota (along with most other states) calculates reimbursement rates by reference to a formula rather than a fixed amount, the United States explains that the First DataBank settlement simply changed a component in that formula, such that "Minnesota's methods and standards for setting prescription drug payment remain the same." (*Id.* at 7.)

The United States argues that federal law requires that the State amend its plan "whenever necessary to reject (i) Changes in federal law . . .; or (ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program," but nothing "requires a new plan amendment when published price points fluctuate." (*Id.* at 11.) Minnesota estimates a drug's "actual acquisition cost" by discounting the drug's AWP by fifteen percent. (*Id.* at 10.) Minnesota obtains the AWPs it uses in this calculation from First DataBank, but there is no guaranty that the AWP published by First

---

[13](...continued)
amount, be it the previous 14 percent or the present 15 percent, would provide a reimbursement rate that actually reflected the participating pharmacies' costs plus a reasonable profit so as to satisfy Subsection (30)(A)'s equal access mandate.

DataBank is accurate. *New England Carpenters Health Benefits Fund v. First DataBank*, 602 F. Supp. 2d 277, 279 (D. Mass. 2009) (explaining that AWP "does not necessarily bear any relationship to any prices actually charged in the marketplace"). And as the First DataBank settlement reflects, the AWP for many drugs appears to have been inflated for some time. *National Ass'n of Chain Drug Stores v. New England Carpenters Health Benefits Fund*, 582 F.3d 30, 41 (1st Cir. 2009) ("The bulk of the inflated AWP figures went into effect in 2001.").

At least one court has thus ruled that the four-percent cut resulting from the First DataBank settlement regarding its AWP computations provides no basis for a Supremacy Clause claim. *National Association of Chain Drug Stores v. Schwarzenegger*, ___ F. Supp. 2d ___, 2009 WL 5253371 (C.D. Cal. Dec. 22, 2009) (denying preliminary injunction as plaintiffs could not demonstrate likelihood of success on claims confined to reduction in AWP due to settlement). But here, the fact that the four-percent cut does not emanate from any overt State decision to reduce its reimbursement rates does not compel this Court to conclusively hold that no preemption claim is presented because Secretary Sebelius also rejected the requests of several pharmacy associations to instruct the "States to modify their reimbursement rates" based on that settlement. (Doc. No. 53, Ex. 4.) On September 8, 2009, three pharmacists associations–including two of the Plaintiffs here, National Community Pharmacists Association and National Association of Chain Drug Stores–wrote Secretary Sebelius requesting, in effect, that she direct that those States using AWPs impacted by the settlement maintain the pre-settlement AWPs. (*Id.*)

The Secretary's response, dated October 28, 2009, noted that because AWP did not accurately reflect actual drug prices, the reduction was in the public interest. In fact, "reports issued by the Office of Inspector General of the Department of Health and Human Services" confirmed the findings of the settlement that reimbursements had often exceeded pharmacies' actual acquisition costs. Perhaps most importantly, the debate over AWP, as published by First DataBank, is somewhat incongruent with the mandate of Subsection (30)(A) because the "States continue to have the obligation to appropriately determine EAC [Estimated Acquisition Costs] consistent with the regulations." *Id.* Thus, the Secretary found it unnecessary to instruct the States to take any specific action with respect to the settlement agreements. But again, the present record is far from optimal, if not simply inadequate, to conclusively determine on the present Rule 12(c) motion that no Supremacy Clause claim lies with respect to the four-percent cut, either alone or in conjunction with the one-percent cut.[14]

In sum, although Plaintiffs have offered no basis to reject either the Secretary's

---

[14] Insofar as the State submitted its proposed amended plan on September 1, 2009, such that the State's proposal was pending while the Secretary considered and rejected the industry's September 8 request regarding the First DataBank settlement, the relevant chronology might plausibly support the conclusion that the Secretary's subsequent November 18, 2009, approval of the one-percent cut was made with full knowledge of the four-percent cut resulting from the First DataBank settlement. But again, the present record does not definitely answer such questions. And regardless of whether the two reductions should be viewed as cumulative cuts of the same kind or as two separate and different changes, the ultimate issue is whether the resulting reimbursement rate–whatever changes were made to the various factors involved in arriving at that rate–satisfies Subsection (30)(A).

approval of the one-percent reduction as implemented by the State's plan or the Secretary's rejection of any purported need to reverse the four-percent reduction emanating from the First DataBank settlement, the present record does not provide an appropriate basis on which to conclusively reject Plaintiff's Supremacy Clause claims. The Court concludes that the parties should conduct limited discovery tailored to the issue of the Secretary's basis for those decisions.[15]

III. Plaintiffs Are Not Entitled To A Preliminary Injunction

In light of this Court's conclusions that Plaintiffs may not proceed on their Section 1983 claim or any of their state-law claims, and that–at least on the present record–it is far from clear that they could proceed on their Supremacy Clause claims, Plaintiffs have not demonstrated any likelihood of success on the merits. While Plaintiffs' motion for a preliminary injunction must therefore be denied, the denial is without prejudice, however, with respect to their Supremacy Clause claims.

CONCLUSION

The Eleventh Amendment prohibits suit in federal court against the Minnesota

---

[15] Finally, Plaintiffs request that if the Court finds their Complaint insufficient in any respect, it should grant them leave to amend. But the present motion is not one to dismiss for failure to state a claim under Rule 12(b)(6), a motion that challenges the formal sufficiency of a pleading, and the court has not found the Complaint deficient. Rather, the motion is one for judgment on the pleadings, and thus comparable to a summary judgment motion insofar as it seeks a judgment on the merits. As such, there is no basis to permit amendment of the Complaint based simply on the outcome of that motion. Plaintiffs' claims largely fail as a matter of law on their merits, not for any deficiency in the form of the Complaint. Nevertheless, if Plaintiffs believe amendment of their Complaint is warranted, they may file a motion requesting leave to amend.

Department of Human Services as well as any such suit based on state-law claims. Subsection (30)(A) creates no enforceable individual rights on which to premise an action under Section 1983. Finally, while Plaintiffs' claims based on the Supremacy Clause likely fail because the federal Secretary's approval of the State Plan is entitled to deference, Plaintiffs may proceed with limited discovery focused on the basis of that approval. The Court will entertain a motion for summary judgment following that discovery.

Based on the foregoing, and all the files, records and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' motion for judgment on the pleadings (Doc. No. [17]) is **GRANTED IN PART** (insofar as it seeks judgment on the Section 1983 and state-law claims) and **DENIED IN PART** (insofar as it seeks judgment on the Supremacy Clause claims);

2. Plaintiffs' state-law claims (Counts VI, VII and VIII) are **DISMISSED WITHOUT PREJUDICE** (to their being filed in state court);

3. Plaintiffs may conduct, following entry of an appropriate scheduling order, limited discovery focused on the basis of the Secretary's approval of the State plan and her rejection of the request to direct the States to compensate for the four-percent cut resulting from the First DataBank settlement; and

4. Plaintiffs' motion for a preliminary injunction (Doc. No. [13]) is **DENIED**.

Dated: February 10, 2010

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge